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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,419	11/12/2003	Jingkun Li	19596-0551 (45738-294417)	7609
23370	7590	12/08/2004	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/712,419	Applicant(s) LI, JINGKUN	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment filed on 29 October 2004 has been received. Claims 11-13 have been amended. Claims 1-13 are pending.
2. The text of those US codes not found in this office action may be found in a previous office action.

#### *Claim Rejections - 35 USC § 112*

3. Claims 8 and 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 does not limit the scope of claim 1 from which it depends.

#### *Claim Rejections - 35 USC § 102*

4. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Noda et al (US 5,900,379) for reasons of record which are reiterated herein below.

Noda discloses a test kit comprising a lateral flow device having a section that is removable. The removable section comprises a capture region where immobilized antibodies are used to capture an analyte. See column 5, lines 35-44, and column 11, example 1.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazar et al (US 6,277,818 B1) for reasons of record which are reiterated herein below.

Mazar discloses a method for isolating or enriching uPAR-expressing cells from a cell mixture, comprising: contacting the cell mixture with a binding compound that is bound to a solid support such as a resin, flat sheet, test strip, etc; separating cells from the ligand thereby

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enriching or isolating the cells. See column 7, lines 8-26; column 22, line 41 through column 23, lines 24. Mazar also discloses further enriching the cells by plating and growing in appropriate medium.

6. Claims 1-4 and 7-13 are rejected under 35 U.S.C. 102(e) as being anticipated by LaBorde (US 6,607,922).

LaBorde discloses an immunochromatographic assay using superparamagnetic beads or particles coupled with antibodies to capture analytes in a sample. The particles are disposed on a test strip that can be removed from a support member for archival or analysis by appropriate means. See column 2, lines 5-15; column 3, lines 13-30; and column 4, lines 13-17. Even though LaBorde does not specifically teach a test kit comprising such a device; LaBorde anticipates the instant kit claim because it is nothing more than the device itself with no additional components.

#### *Response to Arguments*

7. Applicant's arguments filed 29 October 2004 have been fully considered but they are not persuasive.

Applicant argues that Noda does not anticipate the claims because Noda fails to teach the removal of the membrane immunoassay (the portion containing the bound analyte) from the cassette.

This argument has been fully considered, however, it is noted that claims 9 and 10 are directed to a kit comprising a device where a portion of the device comprises an immobilized binding partner for the analyte (claim 9). Noda teaches such a device. The intended use recited in claim 9 is not given patentable weight.

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The device of claim 10 is recited as comprising structural features that facilitate the separation of the portion containing the bound analyte *from at least a part of the device*. Noda anticipates this device. Noda teaches that the portion containing the bound analyte may be separated from the absorbent materials which is interpreted as "a part of the device".

Applicant argues that Mazar does not anticipate the claims because Mazar teaches removing the bound cells from the ligand thereby isolating or enriching the cells. In contrast, the instant claims do not require the removal of the analyte from the capture immobilized binding partner.

This argument is not persuasive because the opening comprising language of the claims does not exclude additional steps. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) "The transition comprising" in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Finally, Applicant argues that LaBorde does not anticipate the claims because LaBorde requires the removal of the entire test strip from the housing and not only a portion of the test strip from the rest of the test strip as claimed.

This argument is not persuasive, the claims recite removal of the portion containing the bound analyte from at least a part of the device. Therefore, the removal of the test strip (containing the portion having bound analyte) from the housing meet this limitation of "at least a part of the device".

#### *Conclusion*

**8. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**9.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
11/29/04